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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,220	04/17/2008	Catherine Romin	BJS-1487-29	5743
23117 7590 02/04/2009 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
HUYNH, PHUONG N				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
02/04/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/588,220

**Applicant(s)**

RONIN ET AL.

**Examiner**

PHUONG HUYNH

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 49-100 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 49-100 are pending.

Applicant's election with traverse of Group I, Claims 49-75 and 97-99 drawn to a process for screening glycoform specific antibodies directed against a specific glycoform of TSH, filed November 17, 2008, is acknowledged.

However, the following is noted.

- This application contains claims directed to the following patentably distinct species of glycoform specific second glycoprotein identifiable in claims 51, 52, 53, 54, 55 and 56 for the claimed process, for example.
- This application further contains claims directed to the following patentably distinct species of the process that requires glycosylation state of the second glycoprotein obtained by a specific combination of enzymatic modification identifiable in claims 60, 61, 64, 65, 97 and 98 and lectin fractionation identifiable in claims 59, 60, 61, 63, 64, 65 for the claimed process, for example.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics. For example, the process requires distinct enzyme modification such as neuraminidase, fucosidase, glycosyltransferase, sialyl transferase, fucosyl transferase, or neuraminidase, which catalyze the specific sugar transfer, in combination with distinct lectin fractionation such as ConA, Lentil lectins, Ulex lectin, ricin, limulin or Sambucus nigra lectin, which binds distinct sugar such as mannose, fucose, galactose, or sialic acid.

Further, the process requires that the species of antibodies to bind to distinct glycoform of glycoprotein identifiable by branching state and fucosylation, or branching state and sialylation state or branching state, fucosylation and sialylation state of any second glycoprotein such as the alpha chain or beta chain of TSH, LH, FSH or placental hCG. The species of antibodies have different binding specificity, different binding affinity, and these antibodies have different

structure, i.e., different heavy chain and light chain CDRs as shown by their lack of binding to the same glycoprotein at the same time (claims 66-67). Therefore, they are patentably distinct.

In addition to the elected Group I, Applicant is further required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of the process that requires a specific glycosylation state of the second glycoprotein obtained by a specific combination of (1) a specific enzymatic modification identifiable in claims 60, 61, 64, 65, 97 and 98, (2) a specific lectin fractionation identifiable in claims 59, 60, 61, 63, 64, and 65 for the claimed process, for example and (3) a distinct species of glycoform specific second glycoprotein identifiable in claims 51, 52, 53, 54, 55 and 56 to which the antibody binds in consonant with the elected combination of enzymatic modification identifiable in claims 60, 61, 64, and 65 and lectin fractionation identifiable in claims 59, 60, 61, 63, 64, 65 for the claimed process, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 49, 50, and 75 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species of glycoprotein require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Art Unit: 1644

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.

Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/

Primary Examiner, Art Unit 1644

January 29, 2009